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Pages 11-12

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
TightRope™ Syndesmosis Device

NAME OF SPONSOR:

Arthrex, Inc.
1370 Creekside Boulevard
Naples, Florida 34108-1945

510(K) CONTACT:

Sally Foust, RAC
Sr. Regulatory Affairs Specialist
Telephone: (239) 643-5553 extension 1251
FAX: (239) 598-5539

TRADE NAME:

TightRope™ Syndesmosis Device

COMMON NAME:

Button/Suture

DEVICE PRODUCT CODE/CLASSIFICATION:

HWC: Single/multiple component metallic bone fixation appliances and accessories:
21 CFR 888.3030

MBI: Fastener, Fixation, Nondegradable, Soft Tissue
Smooth or threaded metallic bone fixation fastener: 21 CFR 888.3040

GAT: Nonabsorbable poly (ethylene terephthalate) surgical suture: 21 CFR 878.5000

PREDICATE DEVICES

K033717: TranSet™ Fracture Fixation System (Bonutti)
K963172: 4.0 / 4.5 mm Screw (Synthes)
K003077: SmartScrew™. Bionx Implants, Ltd. (Linvatec)
K030900, OTPS™ Biodegradable Fixation System (Inion Ltd.)
K984550, EndoButton (Smith & Nephew)
pre-1976, Kirschner (K) Wire (Synthes)

DEVICE DESCRIPTION AND INTENDED USE

The TightRope™ Syndesmosis Device is designed as two differently sized metal buttons, both stainless steel or both titanium, and FiberWire™ suture. The buttons are pre-threaded with FiberWire suture, looped twice through the buttonholes. A long straight needle with pull-through FiberWire suture is also looped through the leading button.

The Arthrex TightRope™ Syndesmosis Device is intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as an adjunct in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting.

Specifically, the Arthrex TightRope™ Syndesmosis Device is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures.

SUBSTANTIALLY EQUIVALENCE

Arthrex has determined that the TightRope™ Syndesmosis Device is substantially equivalent to the predicate devices where basic features and intended uses are the same. Any design differences between the Arthrex TightRope™ Syndesmosis Device when compared to predicate devices used in the standard medical practice for the treatment of syndesmosis are considered minor and do not raise any questions concerning safety and effectiveness. Any differences have been found to have no apparent effect on the performance, function, or intended use of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 16 2005

Ms. Sally Foust, RAC
Sr. Regulatory Affairs Specialist
Arthrex, Inc.
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K043248
Trade/Device Name: Arthrex TightRope™ Syndesmosis Devices
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HTN
Dated: February 7, 2005
Received: February 8, 2005

Dear Ms. Foust:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

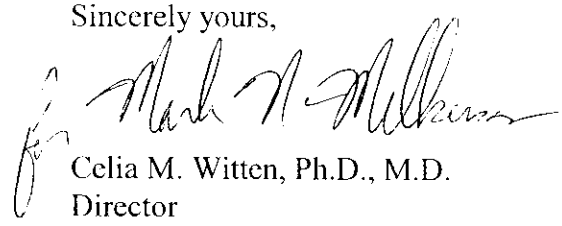
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet addresshttp://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K043248

Device Name: Arthrex TightRope™ Syndesmosis Device

Indications for Use:

The Arthrex TightRope™ Syndesmosis Device is intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as an adjunct in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting.

Specifically, the Arthrex TightRope™ Syndesmosis Device is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures.

Prescription Use Yes (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use No (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K043248